

REMARKS

In the Office Action under reply, the pending claims have been rejected as follows:

1. Under 35 U.S.C. §112, second paragraph, as indefinite for their use of the term “solvent” with respect to methylborinic acid (claims 1 and 5);
2. Under 35 U.S.C. §101 as lacking utility (claims 1, 5-8, 10-17, 19-31, 62, and 63);
3. Under the judicially created doctrine of obviousness-type double patenting over
 - a. claims 1-11 of co-pending U.S. Patent Application No. **11/253,322**;
 - b. claims 1-30 of co-pending U.S. Patent Application No. **10/629,368**;
 - c. claims 11, 14-27, 29, 30, 34, 36, and 37 of co-pending U.S. Patent Application No. **11/070,768**;
 - d. claims 2-4 of U.S. Patent No. **7,109,180**;
 - e. claims 5-8 and 10-22 of U.S. Patent No. **7,183,264**;
 - f. claims 10-24 of U.S. Patent No. **7,144,872**;
 - g. claims 9, 10, and 16 of U.S. Patent No. **6,642,210**;
 - h. claims 2-4 of U.S. Patent No. **6,770,634**;
 - i. claims 11-13 of U.S. Patent No. **6,403,567**; and
 - j. claims 2-4 of co-pending U.S. Patent Application No. **11/588,834**;
 - k. claims 29-31 of co-pending U.S. Patent Application No. **11/522,120** (all claims);
4. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. **6,214,807**, to Zablocki et al. (all claims); and
5. Under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. **6,403,567**, to Zablocki et al. (all claims).

In the present amendment, claims 1, 5-8, 10-17, 19-31, 62, and 63 have been canceled and new claims 64-85 have been added. Thus, claims 64-85 are pending in the application.

The Examiner's rejections and objections are addressed, in part, by the above-amendments and are otherwise traversed by the arguments presented below.

THE AMENDMENTS TO THE CLAIMS AND THE NEW CLAIMS

In an effort to streamline prosecution, all previously pending claims have been cancelled and new claims 64-85 have been. The following table indicates the location of support for the new claims in the previously pending claims.

New Claim	Previously Pending Claim
64	1
65	10
66	5
67	8
68	15
69	7
70	12
71	14
72	11
73	13
74	63
75	16
76	16
77	17
78	19
79	20
80	21
81	23
82	24
83	25
84	26
85	27
86	28
87	29
88	30
89	31

No new matter has been entered by the redrafting of the new claims although some minor alterations were made to correct grammatical issues and to improve clarity. The new claims also focus on the A_{2a} receptor agonist CVT-3146. Cancellation of the subject matter directed the A_{2a}

receptor agonist CVT-3033 is without prejudice and is not a reflection of any intention to abandon any previously claimed subject matter or as acquiesces in any rejection or record. Applicants specifically reserve the right to fill a continuing application directed to the CVT-3033 material.

THE REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected now cancelled claims 1 and 5 as indefinite for their description of the methylboronic acid as a co-solvent given that the substance is solid at room temperature. As claims 1 and 5 have been cancelled the rejection is now moot and its withdrawal is respectfully requested

Applicants wish to point out that new independent claims 64 and 66, which correspond to previously pending claims 1 and 5, recite that the co-solvent comprising a non-toxic amount of methylboronic acid is in solution. Support for this language is found in the application on page 13 lines 18-23.

THE REJECTION UNDER 35 U.S.C. §101

The Examiner has rejected now cancelled claims 1, 5-8, 10-17, 19-31, 62, and 63 as lacking utility in view of the recognized toxicity of two of the possible co-solvent components. As claims 1, 5-8, 10-17, 19-31, 62, and 63 have been cancelled the rejection is now moot and its withdrawal is respectfully requested

Applicants wish to point out that the new claims specify that the co-solvent comprising a non-toxic amount of methylboronic acid in solution or a non-toxic amount of borate buffer. Support for this language is found throughout the application as it has always been intended for use as a pharmaceutical.

THE OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

The Examiner has rejected all claims under the judicially created doctrine on obviousness-type double patenting over 11 different patents and/or applications. Of these 11 rejections, 3 are based on the reference's disclosure of CVT-3033. Specifically, the following rejections are based only on the claiming of CVT-3033:

1. claims 2-4 of U.S. Patent No. **7,109,180**;
2. claims 2-4 of U.S. Patent No. **6,770,634**; and
3. claims 29-31 of co-pending U.S. Patent Application No. **11/522,120** (all claims).

As this aspect of the present application is no longer encompassed by the pending claims, the rejections based on CVT-3033 are now moot.

With respect to the rejection over U.S. Patent Application No. **11/253,322**, Applicants submit that this rejection is in error. The present application has a filing date of January 27, 2004, while the cited reference has a filing date of October 19, 2005. Given that the present application antedates the cited application, the rejection is in error and its withdrawal is respectfully requested.

The Applicant traverses the remaining obviousness-type double patenting rejections. When claims of a patent application are patentably distinct from claims of a first or earlier patent or patent application, then the claims are not properly rejected for double patenting. An obviousness type double patenting analysis requires the comparison of one or more claims of an applicant's earlier patent or patent application with one or more pending application claim to determine if the prior claim along with any cited prior art renders the later application claims obvious. The specification of the cited commonly owned patents or patent applications may not be used in an obviousness type double patenting rejection as prior art. Instead, the examiner may only resort to the specifications of the commonly owned patents and application in order to understand the meaning of the terms of any claims cited in the double patenting rejection.

In this case, the examiner has not relied upon any prior art in the obviousness type double patent rejections. Instead, the examiner relies only upon the claims of the earlier patents and patent applications to render the pending claims obvious. Therefore, in order to establish a *prima facie*

case of obviousness, the examiner must show that all of the features of the pending claims are obvious ONLY from the cited patent or application claims when they are properly construed. When this proper analysis is performed, it is clear that the presently claimed formulation – which requires (1) at least one liquid carrier; (2) at least one co-solvent; and (3) a pH within a specified range - is not remotely disclosed or suggested in the cited patent and application claims. Indeed none of the patent or application claims the examiner cites disclose or suggest the use of at least one co-solvent or the pH range. The examiner has, therefore, failed to establish a *prima facie* case of obviousness of the pending claims in view of claims of U.S. patents 7,183,264; 7,144,872; 6,642,210; and 6,403,567, nor in view of U.S. patent application nos. 10/629,368; 11/070,768; and 11/588,834. For this reason at least, the obviousness-type double patent rejections in view of these patents and applications must be withdrawn.

THE REJECTION UNDER 35 U.S.C. §102(B)

The Examiner has rejected now cancelled claims 1, 5-8, 10-17, 19-31, 62, and 63 as anticipated by the disclosure of U.S. Patent No. **6,214,807** to Zablocki et al. (the '807 patent). Alternatively the Examiner cites the related PCT Publication WO 00/78778. The Examiner specifically cites these references for their disclosure of the compound CVT-3033. As this compound is no longer within the scope of the pending claims, the rejection is now moot and Applicants respectfully request that it be withdrawn.

THE REJECTION UNDER 35 U.S.C. §102(E)

The Examiner has rejected now cancelled claims 1, 5-8, 10-17, 19-31, 62, and 63 as anticipated by the disclosure of U.S. Patent No. **6,403,567** to Zablocki et al. (the '567 patent). Alternatively the Examiner cites the related PCT Publication WO 00/78779. The Examiner specifically cites the reference for its disclosure of the compound CVT-3146 and urges Applicants to provide appropriate disclosure of the unexpected results in support of patentability. Applicants respectfully disagree with both the rejection and the Examiner's suggestion that unexpected results would somehow serve to remove a rejection based on anticipation.

As an initial point, Applicants wish to remind the Examiner that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation **the Examiner must therefore show that each and every element of the pending claims is described** in the reference. This is simply not the case in the present instance.

Independent claims 64 and 74 each contain an element requiring that the pH of the claimed pharmaceutical composition be within a specific range. Claim 64 recites a pH ranging from about 8-5 to about 10 and claim 74 recites a pH ranging from about 6 to about 8. ***There is no express disclosure of either of these pH ranges in the '567 patent.*** While it is true that the '567 patent discloses the compound CVT-3146 and its use in stimulating coronary vasodilatation for purposes of imaging the heart in a mammal, ***there is no teaching regarding pH in the '567 patent whatsoever in the '567 patent.*** Although various buffers and excipients are disclosed, those buffers and excipients can be used to produce formulations have a wide range of pH values and thus ***there is no inherent disclosure of the claimed pH ranges either.*** The '567 patent clearly does not anticipate the pending claims and the rejection under 35 U.S.C. §102(e) is in error.

Applicant's believe that the Examiner was on some level aware of the non-applicability of a rejection under 35 U.S.C. §102(e) as the Examiner requested that some evidence of unexpected results be provided. The submission of evidence of unexpected results may be used to overcome an obviousness rejection under 35 U.S.C. §103(a). ***Applicants wish to point out, however, that a rejection under 35 U.S.C. §103(a) would also be in error in this instance.*** While the '567 patent might constitute a basis for a rejection under 35 U.S.C. §103(a), under the provisions of 35 U.S.C. §103(c):

(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Applicants formally state that at the time the claimed invention was made it was subject to an obligation of assignment to CV Therapeutics, Inc. the owner of the '567 patent. Accordingly, a rejection under 35 U.S.C. §103(a) would also be in error.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is in order and is respectfully requested.

CONCLUSION

For the foregoing reasons, Applicants submit that the claims are in condition for allowance. A Notice of Allowance is requested, and a prompt mailing thereof would be much appreciated.

Should the Examiner have any questions, he is invited to contact the undersigned attorney at (312) 913-2123.

Respectfully submitted,

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